

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 52-53, 55-62 and 64-75 are pending. Non-elected claims 70-75 were withdrawn from consideration by the Examiner. Their rejoinder is requested after claim 61 is allowed because the withdrawn claims are directed to methods of using the seed according to claim 61.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. In particular, (i) the Examiner's suggestions for clarifying the claims are adopted in part and (ii) the limitation of claims 54 and 63 is incorporated to clarify that the DNA sequences encoding the signal sequence and the lysosomal enzyme are in-frame fused.

Claims 53-61 and 68 were objected to as allegedly informal. They are amended to correct the informalities. Withdrawal of the objections is requested.

35 U.S.C. 112 – Definiteness

Claims 59-63 and 68 were rejected under Section 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse because the claims are amended to correct the informalities.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claims 52-69 were rejected under Section 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants traverse because the claims are amended to adopt the Examiner's suggestion of subject matter that is adequately described by the present specification.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 52-69 were rejected under Section 112, first paragraph, because it was alleged that the specification does not reasonably provide enablement for a transformed plant that comprises an expression vector comprising any promoter, any signal sequence, and a sequence encoding a lysosomal enzyme which does not necessarily have to be fused in-frame to the signal sequence. Applicants traverse because the claims are amended to adopt the Examiner's suggestion of subject matter that is adequately enabled by the present specification.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. A claimed invention is

unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing the legal standard provided in *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. See *id.* at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning"). Thus, a rejection under Section 103(a) requires "some rationale, articulation, or reasoned basis to explain why the conclusion of [prima facie] obviousness is correct." *Kahn*, 78 USPQ2d at 1335; see *KSR*, 82 USPQ2d at 1396. But a claim which is directed to a combination of prior art elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1396. Finally, a determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 52-69 were rejected under Section 103(a) as allegedly unpatentable over Radin et al. (U.S. Patent 5,929,304) in view of Watanabe et al. (GenBank Accession D16107), further in view of Fogher (WO 00/04146), and further in view of Whitelam et al. (J. Sci. Fodd Agric. 68:1-9, 1995). Applicants traverse.

Radin discloses expression from an inducible promoter in different plant organs, but the inducible promoter would not be useful for in-seed expression for technical reasons. Moreover, enzymes cited in this document (e.g., glucocerebrosidase) were not stable in leaf, stem, flower, and fruit. Therefore, as of the filing of this application, a reasonable expectation of success was lacking to use seeds as an effective and stable storage organ for enzymes by selecting and using specific promoters.

Watanabe discloses that the soybean basic 7S globulin promoter has an expression pattern unusual for a storage protein and suggests that the gene encodes a type of heat shock protein. Fogher discloses in-seed expression of human lactoferrin using the soybean basic 7S globulin promoter. But lactoferrin is not an enzyme. It is also relatively stable as compared to lysosomal enzymes. Given their description of this promoter, one of ordinary skill in the art would not have found a reasonable expectation of success to use the promoter to express a lysosomal enzyme because there is no indication in the prior art that the enzyme could be purified in active form from seeds.

Whitelam discloses that expression of recombinant enzymes in seeds would be desirable, but the cited documents leaves open the problems solved by the present invention. Therefore, Applicants submit that the Radin, Watanabe, Fogher, and Whitelam documents cannot be considered to suggest the pending claims.

Withdrawal of the Section 103 rejection is requested because the claimed invention would not have been obvious to the ordinarily skilled artisan at the time Applicants made their invention.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Gary R. Tanigawa/
Gary R. Tanigawa
Reg. No. 43,180

901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100